

GAU 1643



PATENT  
Attorney Docket No. EXT-036

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS: Shuber  
SERIAL NO.: 09/514,865 GROUP NO.: 1643  
FILING DATE: 2/28/00 EXAMINER: Not yet assigned  
TITLE: METHODS FOR DISEASE DETECTION

**INFORMATION DISCLOSURE STATEMENT**

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

In accordance with the provisions of 37 C.F.R. §1.97, Applicants hereby make of record the references listed on the accompanying Form PTO-1449 for consideration by the Examiner in connection with the examination of the above-identified patent application. Copies of the references are enclosed.

**REMARKS**

In accordance with the provisions of 37 C.F.R. §1.97, this statement is being filed (CHECK ONE):

- (1) within three (3) months of the **Filing Date** or before the mailing date of the **First Office Action** on the merits; or
- (2) after the period defined in (1) but before the mailing date of a **Final Rejection** or **Notice of Allowance**, and
- the requisite Statement is below, **OR**
- the requisite fee under Rule 1.17(p), namely **\$240.00**, is included herein, or
- (3) after the mailing date of a **Final Rejection** or **Notice of Allowance** but before the payment of the **Issue Fee**, **AND**
- Applicant hereby Petitions the Commissioner to accept and consider the attached Information Disclosure Statement, **AND**
- the requisite Statement is below, **AND**
- the requisite petition fee due under Rule 1.17(i)(I), namely **\$130.00** is included herein.

Information Disclosure Statement

Serial No.: 09/514,865

Page 2 of 2

It is respectfully requested that each of the references shown on the attached Form PTO-1449 be made of record in this application.

**STATEMENT**

As required under §1.97(e), Applicants, through the undersigned, hereby state either that [check the appropriate space]:

1. [E]ach item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application **not more than** three months prior to the filing date of the Information Disclosure Statement; or
2. [N]o item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and to the knowledge of the person signing this Statement after making reasonable inquiry, no item of information contained in the Information Disclosure Statement was known to **any** individual designated in §1.56(c) **more than** three months prior to the filing of the Information Disclosure Statement.

**FEE AUTHORIZATION**

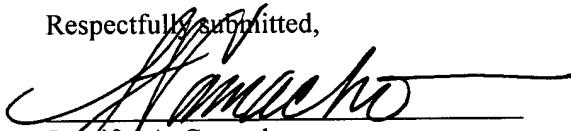
Should any fee associated with the submission of this paper not be attached hereto as a check, the Commissioner is authorized to charge the missing fee to our Deposit Account, No. 20-0531. Any overpayments should be credited to said Deposit Account.

Date: 6/23/00  
Reg. No. 48,526

Tel. No.: (617) 248-7476  
Fax No.: (617) 248-7100

479JAC2457/2.A1022636-1

Respectfully submitted,

  
Jennifer A. Camacho  
Attorney for Applicants  
Testa, Hurwitz, & Thibeault, LLP  
High Street Tower  
125 High Street  
Boston, Massachusetts 02110



PATENT  
Attorney Docket No. EXT-036

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS: **Shuber**  
SERIAL NO.: **09/514,865** GROUP NO.: **1643**  
FILING DATE: **February 28, 2000** EXAMINER: **Not yet assigned**  
TITLE: **Methods for Disease Detection**

**CERTIFICATE OF FIRST CLASS MAILING UNDER 37 C.F.R. 1.8**

I hereby certify that this correspondence, and any documents referred to as enclosed herein, are being deposited with the United States Postal Service as first class mail, postage prepaid, in an envelope addressed to the Assistant Commissioner for Patents, Washington, DC 20231 on this 26<sup>th</sup> day of June, 2000.

*Wendy Martin*  
Wendy Martin

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

Submitted herewith are the following:

Transmittal Form (1 page); Information Disclosure Statement (2 pages); Form PTO-1449 (11 pages); Cited references A1-A46, B1-B42 and C1-C94; And return receipt postcard.

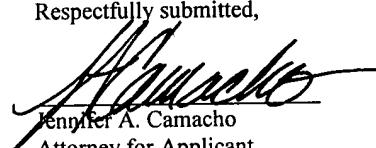


# TRANSMITTAL FORM

Application Serial Number	09/514,865
Filing Date	February 28, 2000
First Named Inventor	Shuber
Group Art Unit	1643
Examiner Name	Not yet assigned
Attorney Docket No.	EXT-036

## ENCLOSURES (check all that apply)

<input type="checkbox"/> Fee Transmittal Form <ul style="list-style-type: none"> <li><input type="checkbox"/> Check Attached</li> <li><input type="checkbox"/> Copy of Fee Transmittal Form</li> </ul>	<input type="checkbox"/> Copy of Notice to File Missing Parts of Application (FORM PTO-1533) <ul style="list-style-type: none"> <li><input type="checkbox"/> Formal Drawing(s)</li> <li><input type="checkbox"/> Petition Routing Slip (PTO/SB/69) and Accompanying Petition</li> </ul>	<input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <ul style="list-style-type: none"> <li><input type="checkbox"/> Appeal Communication to Group (<i>Appeal Notice, Brief, Reply Brief</i>)</li> <li><input type="checkbox"/> Status Letter</li> </ul>
<input type="checkbox"/> Amendment/Response <ul style="list-style-type: none"> <li><input type="checkbox"/> Response to Restriction Requirement and Amendment</li> <li><input type="checkbox"/> After Final</li> <li><input type="checkbox"/> Affidavits/declaration(s)</li> </ul>	<input type="checkbox"/> To Convert to a Provisional Application	<input checked="" type="checkbox"/> Return Receipt Postcard
<input type="checkbox"/> Letter to Official Draftsperson including Drawings [Total Sheets _____]	<input type="checkbox"/> Power of Attorney (Revocation of Prior Powers)	<input type="checkbox"/> Certificate of First Class Mailing under 37 C.F.R. 1.8
<input type="checkbox"/> Petition for Extension of Time Under 37 CFR 1.136(a)	<input type="checkbox"/> Terminal Disclaimer	<input type="checkbox"/> Additional Enclosure(s) ( <i>please identify below</i> )
<input checked="" type="checkbox"/> Information Disclosure Statement	<input type="checkbox"/> Executed Declaration and Power of Attorney for Utility or Design Patent Application	
<input checked="" type="checkbox"/> Form PTO-1449	<input type="checkbox"/> Small Entity Statement	
<input checked="" type="checkbox"/> Copies of IDS Citations	<input type="checkbox"/> Request for Refund	
<input type="checkbox"/> Certified Copy of Priority Document(s)	<input type="checkbox"/> After Allowance Communication to Group	
<input type="checkbox"/> Response to Notice to File Missing Parts of Application (FORM PTO-1533)		
<input type="checkbox"/> Declaration and Power of Attorney For Utility or Design Application (4 pages)		

CORRESPONDENCE ADDRESS	SIGNATURE BLOCK
Direct all correspondence to: Patent Administrator Testa, Hurwitz & Thibeault, LLP High Street Tower 125 High Street Boston, MA 02110 Tel. No.: (617) 248-7000 Fax No.: (617) 248-7100	<p>Respectfully submitted,</p> <p>Jennifer A. Camacho Attorney for Applicant Testa, Hurwitz &amp; Thibeault, LLP High Street Tower 125 High Street Boston, MA 02110</p> 



FORM PTO - 1449  INFORMATION DISCLOSURE STATEMENT		ATTORNEY DOCKET NO.: EXT-036  APPLICANT(S): Shuber  SERIAL NO.: 09/514,865  FILING DATE: 2/28/00      GROUP: 1643	
---	--	---	--

## U.S. PATENT DOCUMENTS

EXAM. INIT.		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
	A1	4,333,734	6/8/82	Fleisher			10/8/80
	A2	4,535,058	8/13/85	Weinberg et al.			10/1/82
	A3	4,683,195	7/28/87	Mullis et al.			2/7/86
	A4	4,786,718	11/22/88	Weinberg et al.			8/8/85
	A5	4,857,300	8/15/89	Maksem			7/27/87
	A6	4,871,838	10/3/89	Bos et al.			7/23/85
	A7	4,981,783	1/1/91	Augenlicht			4/16/86
	A8	4,982,615	1/8/91	Sultan et al.			4/18/89
	A9	5,087,617	2/11/92	Smith			2/15/89
	A10	5,126,239	6/30/92	Livak et al.			3/14/90
	A11	5,137,806	8/11/92	LeMaistre et al.			12/11/89
	A12	5,196,167	3/23/93	Guadagno et al.			5/9/91
	A13	5,248,671	9/28/93	Smith			12/9/91
	A14	5,272,057	12/21/93	Smulson et al.			12/21/93
	A15	5,302,509	4/12/94	Cheeseman			2/27/91
	A16	5,330,892	7/19/94	Vogelstein et al.			3/13/91
	A17	5,348,855	9/20/94	Dattagupta et al.			10/4/91
	A18	5,352,775	10/4/94	Albertsen et al.			8/8/91
	A19	5,362,623	11/8/94	Vogelstein et al.			3/31/92
	A20	5,369,004	11/29/94	Polymeropoulos et al.			7/31/92
	A21	5,378,602	1/3/95	Polymeropoulos et al.			11/27/91
	A22	5,380,645	1/10/95	Vogelstein			3/16/89
	A23	5,380,647	1/10/95	Bahar			4/26/93
	A24	5,382,510	1/17/95	Levine et al.			7/10/92
	A25	5,409,586	4/25/95	Kamahori et al.			8/24/93

EXAMINER	DATE CONSIDERED
----------	-----------------

FORM PTO - 1449

## INFORMATION DISCLOSURE STATEMENT

ATTORNEY DOCKET NO.: EXT-036

APPLICANT(S): Shuber

SERIAL NO.: 09/514,865

FILING DATE: 2/28/00

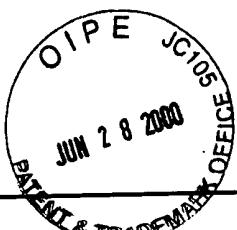
GROUP: 1643

## U.S. PATENT DOCUMENTS

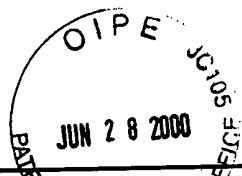
EXAM. INIT.		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
	A26	5,458,761	10/17/95	Kamahori et al.			1/27/95
	A27	5,466,576	11/14/95	Schulz et al.			7/2/93
	A28	5,468,610	11/21/95	Polymeropoulos et al.			6/9/93
	A29	5,468,613	11/21/95	Erlich et al.			3/9/90
	A30	5,489,508	2/6/96	West et al.			3/24/93
	A31	5,492,808	2/20/96	de la Chapelle et al.			5/5/93
	A32	5,496,470	3/5/96	Lenhart			5/27/94
	A33	5,508,164	4/16/96	Kausch et al.			10/29/93
	A34	5,512,441	4/30/96	Ronal			11/15/94
	A35	5,514,547	5/7/96	Balazs et al.			2/4/94
	A36	5,527,676	6/18/96	Vogelstein et al.			3/22/93
	A37	5,532,108	7/2/96	Vogelstein			4/14/94
	A38	5,580,729	12/3/96	Vogelstein			6/24/94
	A39	5,589,335	12/31/96	Kearney et al.			8/11/94
	A40	5,670,325	9/23/97	Lapidus et al.			8/14/96
	A41	5,709,998	1/20/98	Kinzler et al.			12/15/93
	A42	5,710,028	1/20/98	Eyal et al.			10/4/94
	A43	5,741,650	4/21/98	Lapidus et al.			4/21/98
	A44	5,759,777	6/2/98	Kearney et al.			6/2/98
	A45	5,830,665	11/3/98	Shuber et al.			3/3/97
	A46	5,928,870	7/27/99	Lapidus et al.			6/16/97

EXAMINER

DATE CONSIDERED



<b>FORM PTO - 1449</b> <b>INFORMATION DISCLOSURE STATEMENT</b>				<b>ATTORNEY DOCKET NO.: EXT-036</b> <b>APPLICANT(S): Shuber</b> <b>SERIAL NO.: 09/514,865</b> <b>FILING DATE: 2/28/00</b> <b>GROUP: 1643</b>					
<b>FOREIGN PATENT DOCUMENTS</b>									
EXAM. INIT.		DOCUMENT NUMBER	DATE	COUNTRY CODE	CLASS	SUB CLASS	FILING DATE	ABSTRACT ONLY	ENGLISH LANG Y/N
	B1	0 284 362 A2	9/28/88	EP			3/23/88		
	B2	0 337 498 A2	10/18/89	EP			4/17/89		
	B3	WO 90/09455	8/23/90	PCT			2/13/90		
	B4	0 390 323 A2	10/3/90	EP			2/20/90		
	B5	0 390 323 A3	10/3/90	EP			2/20/90		
	B6	0 407 789 A1	1/16/91	EP			6/22/90		
	B7	0 407 789 B1	1/16/91	EP			6/22/90		
	B8	WO 92/13103	8/6/92	PCT			1/16/92		
	B9	WO 92/16657	10/1/92	PCT			3/12/92		
	B10	WO 93/18186	9/16/93	PCT			3/1/93		
	B11	WO 93/20233	10/14/93	PCT			3/22/93		
	B12	WO 94/01447	1/20/94	PCT			7/1/93		
	B13	WO 94/09161	4/28/94	PCT			10/20/93		
	B14	WO 94/10575	5/11/94	PCT			10/29/93		
	B15	WO 94/11383	5/26/94	PCT			11/8/93		
	B16	0 608 004 A2	7/27/94	EP			8/11/87		
	B17	A-11325/95	10/5/94	AU					
	B18	0 259 031 B1	11/9/94	EP			8/11/87		
	B19	WO 95/07361	3/16/95	PCT			9/9/94		
	B20	WO 95/09928	4/13/95	PCT			9/26/94		
	B21	WO 95/09929	4/13/95	PCT			9/26/94		
	B22	0 648 845 A2	4/19/95	EP			7/2/94		
	B23	WO 95/13397	5/18/95	PCT			11/10/94		
	B24	WO 95/15400	6/8/95	PCT			12/5/94		
	B25	WP 95/16792	6/22/95	PCT			12/13/94		NO
<b>EXAMINER</b>					<b>DATE CONSIDERED</b>				



<b>FORM PTO - 1449</b> <b>INFORMATION DISCLOSURE STATEMENT</b>		<b>ATTORNEY DOCKET NO.: EXT-036</b> <b>APPLICANT(S): Shuber</b> <b>SERIAL NO.: 09/514,865</b> <b>FILING DATE: 2/28/00</b> <b>GROUP: 1643</b>	
---	--	---	--

**FOREIGN PATENT DOCUMENTS**

EXAM. INIT.		DOCUMENT NUMBER	DATE	COUNTRY CODE	CLASS	SUB CLASS	FILING DATE	ABSTRACT ONLY	ENGLISH LANG Y/N
	B26	WO 95/18818	7/13/95	PCT			1/3/95		
	B27	WO 95/19448	7/20/95	PCT			1/13/95		
	B28	0 664 339 A1	7/26/95	EP			7/7/94		
	B29	WO 95/25813	9/28/95	PCT			3/17/95		
	B30	WO 95/31728	11/23/95	PCT			5/15/95		
	B31	WO 96/01907	1/25/96	PCT			7/10/95		
	B32	WO 96/06951	3/7/96	PCT			8/31/95		
	B33	WO 96/08514	3/21/96	PCT			9/12/95		
	B34	WO 96/12821	5/2/96	PCT			12/19/95		
	B35	WO 96/13611	5/9/96	PCT			10/27/95		
	B36	WO 96/30545	10/3/96	PCT			2/14/96		
	B37	WO 97/09449	3/13/97	PCT			9/2/96		
	B38	WO 97/09600	3/13/97	PCT			9/5/96		
	B39	WO 97/23651	7/3/97	PCT			12/20/96		
	B40	WO 97/25442	7/17/97	PCT			1/9/97		
	B41	WO 98/38338	9/3/98	PCT			2/27/98		
	B42	WO 98/58081	12/23/98	PCT			6/4/98		

EXAMINER	DATE CONSIDERED
----------	-----------------



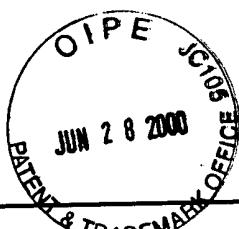
<b>FORM PTO - 1449</b> <b>INFORMATION DISCLOSURE STATEMENT</b>		<b>ATTORNEY DOCKET NO.: EXT-036</b> <b>APPLICANT(S): Shuber</b> <b>SERIAL NO.: 09/514,865</b> <b>FILING DATE: 2/28/00</b> <b>GROUP: 1643</b>
<b>OTHER ART, JOURNAL ARTICLES, ETC.</b>		
<b>EXAM. INIT.</b>		<b>OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)</b>
	C1	Aaltonen <i>et al.</i> (1994) "Replication Errors in Benign and Malignant Tumors from Hereditary Nonpolyposis Colorectal Cancer Patients" <u>Cancer Research</u> 54: 1645-1648
	C2	Aaltonen <i>et al.</i> (1998) "Incidence of Hereditary Nonpolyposis Colorectal Cancer and the Feasibility of Molecular Screening for the Disease" <u>The New England Journal of Medicine</u> 338: 1481-1487
	C3	Ausubel <i>et al.</i> , (1995), <u>Short Protocols in Molecular Biology</u> , 3d ed., pp. 2-3 -2-12, 3-30 -3-33.
	C4	Bertario <i>et al.</i> (1999) "Risk of Colorectal Cancer Following Colonoscopic Polypectomy" <u>Tumori</u> 85: 157-162
	C5	Beskin <i>et al.</i> , (1995), "On the Mechanism of the Modular Primer Effect," <u>Nucleic Acids Research</u> , Vol. 23 No. 15, 2881-2885.
	C6	Blum H.E., (1995) "Colorectal Cancer: Future Population Screening for Early Colorectal Cancer" <u>European Journal of Cancer</u> , Vol. 31A, pp. 1369-1372.
	C7	Bos <i>et al.</i> , (May 28, 1987) "Prevalence of <i>ras</i> Gene Mutations in Human Colorectal Cancers," <u>Nature</u> , Vol. 327, pp. 293-297.
	C8	Caldas <i>et al.</i> , (July 1, 1994) "Detection of K-ras Mutations in the Stool of Patients with Pancreatic Adenocarcinoma and Pancreatic Ductal Hyperplasia" <u>Cancer Research</u> , Vol. 54, pp. 3568-3573.
	C9	Capozzi <i>et al.</i> (1999) "Evaluation of the Replication Error Phenotype in Relation to Molecular and Clinicopathological Features in Hereditary and Early Onset Colorectal Cancer" <u>European Journal of Cancer</u> 35: 289-295
	C10	Cave <i>et al.</i> , (1994) "Reliability of PCR Directly from Stool Samples: Usefulness of an Internal Standard," <u>BioTechniques</u> , Vol. 16, No. 5, pp. 809-810.
	C11	Chapelle (1999) "Testing Tumors for Microsatellite Instability" <u>European Journal of Human Genetics</u> 7: 407-408
	C12	Charlesworth <i>et al.</i> , (September 15, 1994) "The Evolutionary Dynamics of Repetitive DNA in Eukaryotes," <u>Nature</u> , Vol. 371, pp. 215-220.
	C13	Chen <i>et al.</i> (1997) "Microsatellite Instability in Sporadic-Colon-Cancer Patients With and Without Liver Metastases" <u>International Journal of Cancer</u> 74: 470-474
	C14	Coll <i>et al.</i> , (October 1989) "Evaluation of a Rapid Method of Extracting DNA from Stool Samples for Use in Hybridization Assays," <u>Journal of Clinical Microbiology</u> , Vol. 27, No. 10, pp. 2245-2248.
	C15	Coughlin <i>et al.</i> (1999) "Public Health Perspectives on Testing for Colorectal Cancer Susceptibility Genes" <u>American Journal of Preventive Medicine</u> 16: 99-104

<b>EXAMINER</b>	<b>DATE CONSIDERED</b>
-----------------	------------------------



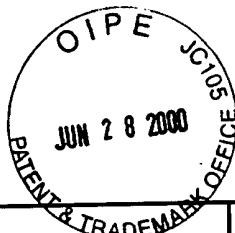
<b>FORM PTO - 1449</b> <b>INFORMATION DISCLOSURE STATEMENT</b>		<b>ATTORNEY DOCKET NO.:</b> EXT-036 <b>APPLICANT(S):</b> Shuber <b>SERIAL NO.:</b> 09/514,865 <b>FILING DATE:</b> 2/28/00 <b>GROUP:</b> 1643
<b>OTHER ART, JOURNAL ARTICLES, ETC. (continued)</b>		
<b>EXAM. INIT.</b>		<b>OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)</b>
	C16	Cunningham C. and M.G. Dunlop, (1996) "Molecular Genetic Basis of Colorectal Cancer Susceptibility," <u>British Journal of Surgery</u> , Vol. 83, pp. 321-329.
	C17	Deng <i>et al.</i> , (December 20, 1996) "Loss of Heterozygosity in Normal Tissue Adjacent to Breast Carcinomas," <u>Science</u> , Vol. 274, pp. 2057-2059.
	C18	Deuter <i>et al.</i> , (1995) "A Method for Preparation of Fecal DNA Suitable for PCR," <u>Nucleic Acids Research</u> , Vol. 23, No. 18, pp. 3800-3801.
	C19	Dib <i>et al.</i> , (March 14, 1996) "A Comprehensive Genetic Map of the Human Genome Based on 5,264 Microsatellites," <u>Nature</u> Vol. 380, pp. 152-154.
	C20	Duffy M.J., (1995) "Can Molecular Markers Now be Used for Early Diagnosis of Malignancy?" <u>Clin. Chem.</u> , Vol. 41, No. 10, pp. 1410-1413.
	C21	Eguchi <i>et al.</i> , (April 15, 1996) "Mutations of the p53 Gene in the Stool of Patients with Resectable Colorectal Cancer," <u>Cancer Supplement</u> , Vol. 77, No. 8, pp. 1707-1710.
	C22	Enari <i>et al.</i> , (January 1, 1998) "A Caspase-Activated DNase that Degrades DNA During Apoptosis, and its Inhibitor ICAD," <u>Nature</u> , Vol. 391, pp. 43-50.
	C23	Fearon, E.R., (1995) "16 Molecular Abnormalities in Colon and Rectal Cancer," <u>The Molecular Basis of Cancer</u> , pp. 340-357.
	C24	Grossman <i>et al.</i> (1988), "Colonoscopic Screening of persons With Suspected Risk Factors for Colon Cancer" <u>Gastroenterology</u> 94: 395-400
	C25	Gyllensten U. B., Allen M., (1995) "Sequencing of In Vitro Amplified DNA," <u>Recombinant DNA Methodology II</u> , (Wu, ed.), pp. 565-578.
	C26	Hasegawa <i>et al.</i> , (1995) "Detection of K-ras Mutations in DNAs Isolated From Feces of Patients with Colorectal Tumors by Mutant-Allele-Specific Amplification (MASA)," <u>Oncogene</u> , Vol. 10, pp. 1441-1445.
	C27	Hoang <i>et al.</i> (1997) "BAT-26, an Indicator of the Replication Error Phenotype in Colorectal Cancers and Cell Lines" <u>Cancer Research</u> 57: 300-303
	C28	Honchel <i>et al.</i> , (1995) "Genomic Instability in Neoplasia," <u>Seminars in Cell Biology</u> , Vol. 6, pp. 45-52.
	C29	Hoss <i>et al.</i> , (September 17, 1992) "Excrement Analysis by PCR" <u>Scientific Correspondence</u> pp. 199.
	C30	Iino <i>et al.</i> (1999) "DNA Microsatellite Instability in Hyperplastic Polyps, Serrated Adenomas, and Mixed Polyps: a Mild Mutator Pathway for Colorectal Cancer?" <u>Journal of Clinical Pathology</u> 52: 5-9

<b>EXAMINER</b>	<b>DATE CONSIDERED</b>
-----------------	------------------------



<b>FORM PTO - 1449</b> <b>INFORMATION DISCLOSURE STATEMENT</b>		<b>ATTORNEY DOCKET NO.: EXT-036</b> <b>APPLICANT(S): Shuber</b> <b>SERIAL NO.: 09/514,865</b> <b>FILING DATE: 2/28/00</b> <b>GROUP: 1643</b>
<b>OTHER ART, JOURNAL ARTICLES, ETC. (continued)</b>		
<b>EXAM. INIT.</b>		<b>OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)</b>
	C31	Iniesta <i>et al.</i> (1998) "Genetic Abnormalities and Microsatellite Instability in Colorectal Cancer" <u>Cancer Detection and Prevention</u> 22: 383-395
	C32	Ishimaru <i>et al.</i> (1995) "Microsatellite Instability in Primary and Metastatic Colorectal Cancers" <u>International Journal of Cancer</u> 64: 153-157
	C33	Jarvinen <i>et al.</i> (1995) "Screening Reduces Colorectal Cancer Rate in Families With Hereditary Nonpolyposis Colorectal Cancer" <u>Gastroenterology</u> 108: 1405-1411
	C34	Jernvall <i>et al.</i> (1999) "Microsatellite Instability: Impact on Cancer Progression in Proximal and Distal Colorectal Cancers" <u>European Journal of Cancer</u> 35: 197-201
	C35	Jessup J.M. and G.E. Gallick, (September/October 1992) "The Biology of Colorectal Carcinoma," <u>Current Problems in Cancer</u> pp. 263-328.
	C36	Jonsson <i>et al.</i> , (January 1995) "From Mutation Mapping to Phenotype Cloning," <u>Proc. Natl. Acad. Sci.</u> , Vol. 92 pp. 83-85.
	C37	Kim <i>et al.</i> (1998) "Microsatellite Instability in Young Patients With Colorectal Cancer" <u>Pathology International</u> 48: 586-594
	C38	Konishi <i>et al.</i> (1996) "Molecular Nature of Colon Tumors in Hereditary Nonpolyposis Colon Cancer, Familial Polyposis, and Sporadic Colon Cancer" <u>Gastroenterology</u> 111: 307-317
	C39	Lamberti <i>et al.</i> (1999) "Microsatellite Instability - a Useful Diagnostic Tool to Select Patients at High Risk for Hereditary Non-Polyposis Colorectal Cancer: A Study in Different Groups of Patients With Colorectal Cancer" <u>Gut</u> 44: 839-843
	C40	Lengauer <i>et al.</i> , (December 17, 1998) "Genetic Instabilities in Human Cancers," <u>Nature</u> , Vol. 396, pp. 643-649.
	C41	Leong <i>et al.</i> , (1993) "Detection of MYCN Gene Amplification and Deletions of Chromosome 1p in Neuroblastoma by In Situ Hybridization Using Routine Histologic Sections," <u>Laboratory Investigations</u> , Vol. 69, No. 1, pp. 43-50.
	C42	Lin <i>et al.</i> (1998) "Colorectal and Extracolonic Cancer Variations in MLH1/MSH2 Hereditary Nonpolyposis Colorectal Cancer Kindreds and the General Population" <u>Diseases of the Colon &amp; Rectum</u> 41: 428-433
	C43	Litja <i>et al.</i> , (1992) "Simultaneous Detection of Two Cystic Fibrosis Alleles Using Dual-Label Time-Resolved Fluorometry," <u>Molecular and Cellular Probes</u> , Vol. 6, pp. 505-512.
	C44	Leonart <i>et al.</i> (1998) "Microsatellite Instability and p53 Mutations in Sporadic Right and Left Colon Carcinoma" <u>American Cancer Society</u> 83: 889-895

<b>EXAMINER</b>	<b>DATE CONSIDERED</b>
-----------------	------------------------



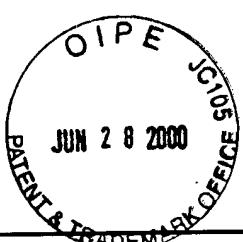
FORM PTO - 1449  INFORMATION DISCLOSURE STATEMENT		ATTORNEY DOCKET NO.: EXT-036  APPLICANT(S): Shuber  SERIAL NO.: 09/514,865  FILING DATE: 2/28/00      GROUP: 1643
OTHER ART, JOURNAL ARTICLES, ETC. (continued)		
EXAM. INIT.		OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)
	C45	Loktionov A. and I. K. O'Neill, (1995) "Early Detection of Cancer-Associated Gene Alterations in DNA Isolated from Rat Feces During Intestinal Tumor Induction with 1,2-Dimethylhydrazine," <u>International Journal of Oncology</u> , Vol. 6, pp. 437-445.
	C46	Loktionov <i>et al.</i> , (February, 1998) "Quantitation of DNA from Exfoliated Colonocytes Isolated from Human Stool Surface as a Novel Noninvasive Screening Test for Colorectal Cancer," <u>Clinical Cancer Research</u> , Vol. 4, pp. 337-341.
	C47	Mao L. <i>et al.</i> , (February 2, 1996) "Molecular Detection of Primary Bladder Cancer by Microsatellite Analysis," <u>Science</u> , Vol. 271, pp. 659-662.
	C48	Myers, R.M., (February 12, 1993) "The Pluses of Subtraction," <u>Science</u> , Vol. 259, pp. 942-943.
	C49	Naber S. P., (December 1, 1994) "Molecular Pathology -- Detection of Neoplasia," <u>New England Journal of Medicine</u> , Vol. 331, No. 22, pp. 1508-1510.
	C50	Nollau <i>et al.</i> , (May 1996) "Isolation of DNA from Stool and Bodily Fluids for PCR Amplification," <u>BioTechniques</u> , Vol. 20, No. 5, pp. 784-788.
	C51	Nollau <i>et al.</i> , (1996) "Detection of K-ras Mutations in Stools of Patients with Colorectal Cancer by Mutant-Enriched PCR," <u>Int. J. Cancer</u> , Vol. 66 pp. 332-336.
	C52	Orlow I., <i>et al.</i> , (October 18, 1995) "Deletion of the p16 and p15 Genes in Human Bladder Tumors <u>Journal of the National Cancer Institute</u> ," Vol. 87, No. 20, pp. 1524-1529.
	C53	Orou, <i>et al.</i> , (1995) "Allele-Specific Competitive Blocker PCR: A One-Step Method With Applicability to Pool Screening" <u>Human Mutation</u> Vol. 6, 163-169.
	C54	Park <i>et al.</i> (1999) "Gene-Environment Interaction in Hereditary Nonpolyposis Colorectal Cancer with Implications for Diagnosis and Genetic Testing" <u>International Journal of Cancer</u> 82: 516-519
	C55	Peltomaki <i>et al.</i> (1997) "Mutations Predisposing to Hereditary Nonpolyposis Colorectal Cancer: Database and Results of a Collaborative Study" <u>Gastroenterology</u> 113: 1146-1158
	C56	Pharmacia, (1998) <u>BioDirectory</u> , pp. 104-109.
	C57	Pharmacia, (1991/1992) <u>Molecular and Cell Biology Catalogue</u> , pp. 8.3-8.6.
	C58	Piao et al., (September 1997) "Relationship between Loss of Heterozygosity of Tumor Suppressor Genes and Histologic Differentiation in Hepatocellular Carcinoma," <u>Cancer</u> , Vol. 80, No. 5, pp. 865-872.

EXAMINER	DATE CONSIDERED
----------	-----------------



<b>FORM PTO - 1449</b> <b>INFORMATION DISCLOSURE STATEMENT</b>		<b>ATTORNEY DOCKET NO.: EXT-036</b> <b>APPLICANT(S): Shuber</b> <b>SERIAL NO.: 09/514,865</b> <b>FILING DATE: 2/28/00</b> <b>GROUP: 1643</b>
<b>OTHER ART, JOURNAL ARTICLES, ETC. (continued)</b>		
<b>EXAM. INIT.</b>		<b>OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)</b>
	C59	Ponz de Leon <i>et al.</i> (1998) "Frequency and Type of Colorectal Tumors in Asymptomatic High -Risk Individuals in Families with Hereditary Nonpolyposis Colorectal Cancer" <u>Cancer Epidemiology, Biomarkers &amp; Prevention</u> 7: 639-641
	C60	Ponz de Leon <i>et al.</i> (1999) "Hereditary Colorectal Cancer in the General Population: From Cancer Registration to Molecular Diagnosis" <u>Gut</u> 45: 32-38
	C61	Pyatt <i>et al.</i> (1999) "Polymorphic Variation at the BAT-25 and BAT-26 Loci in Individuals of African Origin" <u>American Journal of Pathology</u> 155: 349-353
	C62	Raff, M., (November 12, 1998) "Cell Suicide for Beginners," <u>Nature</u> , Vol. 396, pp. 119-122.
	C63	Rashid <i>et al.</i> (1999) "Genetic Epidemiology of Mutated K-ras Proto-Oncogene, Altered Suppressor Genes, and Microsatellite Instability in Colorectal Adenomas" <u>Gut</u> 44: 826-833
	C64	Ravelingien <i>et al.</i> , (1995) "Contribution of Molecular Oncology in the Detection of Colorectal Carcinomas," <u>Acta Gastro-Enterologica Belgica</u> , Vol. 58, pp. 270-273.
	C65	Riegler <i>et al.</i> (1999) "Prevalence of HNPCC in a Series of Consecutive Patients on the First Endoscopic Diagnosis of Colorectal Cancer: A Multicenter Study" <u>Endoscopy</u> 31: 337-341
	C66	Rhyu M. S., (March 6, 1996) "Molecular Mechanisms Underlying Hereditary Nonpolyposis Colorectal Carcinoma," <u>Journal of the National Cancer Institute</u> , Vol. 88, No. 5, pp. 240-251.
	C67	Ridanpaa <i>et al.</i> , (1995) "Detection of Loss of Heterozygosity in the p53 Tumor Suppressor Gene Using a PCR-based Assay," <u>Path. Res. Pract.</u> , Vol. 191, pp. 399-402.
	C68	Rodriguez-Bigas <i>et al.</i> (1997) "A National Cancer Institute Workshop on Hereditary Nonpolyposis Colorectal Cancer Syndrome: Meeting Highlights and Bethesda Guidelines" <u>Journal of the National Cancer Institute</u> 89: 1758-1762
	C69	Salahshor <i>et al.</i> (1999) "Microsatellite Instability in Sporadic Colorectal Cancer is Not an Independent Prognostic Factor" <u>British Journal of Cancer</u> 81: 190-193
	C70	Samowitz <i>et al.</i> (1995) "Microsatellite Instability in Human Colonic Cancer Is Not a Useful Clinical Indicator of Familial Colorectal Cancer" <u>Gastroenterology</u> 109: 1765-1771
	C71	Samowitz <i>et al.</i> (1997) "Microsatellite Instability in Colorectal Adenomas" <u>Gastroenterology</u> 112: 1515-1519
	C72	Samowitz <i>et al.</i> (1999) "BAT-26 and BAT-40 Instability in Colorectal Adenomas and Carcinomas and Germline Polymorphisms" <u>American Journal of Pathology</u> 154: 1637-1641
	C73	Sanger <i>et al.</i> , (December 1977) "DNA Sequencing with Chain-Terminating Inhibitors" <u>Proc. Natl. Acad. Sci. USA</u> , Vol. 74, No. 12, pp. 5463-5467.

<b>EXAMINER</b>	<b>DATE CONSIDERED</b>
-----------------	------------------------

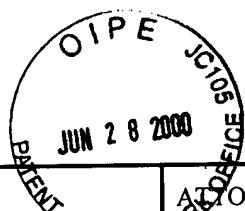


FORM PTO - 1449  INFORMATION DISCLOSURE STATEMENT	ATTORNEY DOCKET NO.: EXT-036  APPLICANT(S): Shuber  SERIAL NO.: 09/514,865  FILING DATE: 2/28/00      GROUP: 1643
---	---

**OTHER ART, JOURNAL ARTICLES, ETC. (continued)**

EXAM. INIT.	OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)
C74	Santagati <i>et al.</i> , (1997) "Quantitation of Low Abundance mRNAs in Glial Cells Using Different Polymerase chain Reaction (PCR)-Based Methods," <u>Elsevier Science - Brain Research Protocols</u> , 217-223.
C75	Segel I., (1976), "Double Label Analysis," <u>Biochemical Calculations</u> , 2d ed., pp. 373-376.
C76	Sidransky, <i>et al.</i> , (April 3, 1992) "Identification of ras Oncogene Mutations in the Stool of Patients with Curable Colorectal Tumors," <u>Science</u> , Vol. 256, pp. 102-105.
C77	Smith-Ravin <i>et al.</i> , (1995) "Detection of c-Ki-ras Mutations in Faecal Samples from Sporadic Colorectal Cancer Patients," <u>Gut</u> , Vol. 36, pp. 81-86.
C78	Syngal <i>et al.</i> (1998) " Benefits of Colonoscopic Surveillance and Prophylactic Colectomy in Patients With Hereditary Nonpolyposis Colorectal Cancer Mutations" <u>Annals of Internal Medicine</u> 129: 787-796
C79	Syngal <i>et al.</i> (1999) "Interpretation of Genetic Test Results for Hereditary Nonpolyposis Colorectal Cancer" <u>JAMA</u> 282: 247
C80	Takeda <i>et al.</i> , (1993) "Detection of K-ras Mutation in Sputum by Mutant-Allele-Specific Amplification (MASA)," <u>Human Mutation</u> , Vol. 2, pp. 112-117.
C81	Thibodeau <i>et al.</i> , (May 7, 1993) "Microsatellite Instability in Cancer of the Proximal Colon," <u>Science</u> , Vol. 260, pp. 816-819.
C82	Vasen <i>et al.</i> (1993) "Surveillance in Hereditary Nonpolyposis Colorectal Cancer: An International Cooperative Study of 165 Families" <u>Diseases of the Colon &amp; Rectum</u> 36: 1-4
C83	Vasen <i>et al.</i> (1998) "A Cost-Effectiveness Analysis of Colorectal Screening of Hereditary Nonpolyposis Colorectal Carcinoma Gene Carriers" <u>American Cancer Society</u> 82: 1632-1637
C84	Vasen <i>et al.</i> (1999) "New Clinical Criteria for Hereditary Nonpolyposis Colorectal Cancer (HNPCC, Lynch Syndrome) Proposed by the International Collaborative Group on HNPCC" <u>Gastroenterology</u> 116: 1453-1456
C85	Villa <i>et al.</i> , (May 1996) "Identification of Subjects at Risk for Colorectal Carcinoma Through a Test Based on K-ras Determination in the Stool," <u>Gastroenterology</u> , Vol. 110, No. 5, pp. 1346-1353.
C86	Vogelstein, B. and Kinzler, K.W., (August, 1999) "Digital PCR," <u>Proc. Natl. Acad. Sci. USA</u> , Vol. 96, pp. 9236-9241.
C87	Wallace <i>et al.</i> , (1979) "Hybridization of Synthetic Oligodeoxyribonucleotides to $\Phi\chi$ 174 DNA: the Effect of Single Base Pair Mismatch," <u>Nucleic Acids Research</u> , Vol. 6, Number 11, pp. 3543-3557.
C88	Walsh <i>et al.</i> , (February 6, 1992) "Preferential PCR Amplification of Alleles: Mechanisms and Solutions," <u>PCR Methods and Applications</u> , pp. 241-250.

EXAMINER	DATE CONSIDERED



<b>FORM PTO - 1449</b> <b>INFORMATION DISCLOSURE STATEMENT</b>		ATTORNEY DOCKET NO.: EXT-036 APPLICANT(S): Shuber SERIAL NO.: 09/514,865 FILING DATE: 2/28/00      GROUP: 1643
<b>OTHER ART, JOURNAL ARTICLES, ETC. (continued)</b>		
<b>EXAM. INIT.</b>		<b>OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)</b>
	C89	Wang <i>et al.</i> , (May 15, 1998) "Large-Scale Identification, Mapping, and Genotyping of Single-Nucleotide Olymorphisms in the Human Genome," <u>Science</u> , Vol. 280, pp. 1077-1082.
	C90	Watson <i>et al.</i> , "Isolation of Differentiality Expressed Sequence Tags from Human Breast Cancer," <u>Advances in Brief XP 000576043</u> , pp. 4598-4602.
	C91	Wijnen <i>et al.</i> (1999) "Familial Endometrial Cancer in Female Carriers of MSH6 Germline Mutations" <u>Nature Genetics</u> 23: 142-144
	C92	Young G.P., and B.H. Demediou, (1992) "The Genetics, Epidemiology, and Early Detection of Gastrointestinal Cancers" <u>Current Opinion in Oncology</u> , Vol. 4, pp. 728-735.
	C93	Zhou <i>et al.</i> (1997) "Allelic Profiles of Mononucleotide Repeat Microsatellites in Control Individuals and in Colorectal Tumors With and Without Replication Errors" <u>Oncogene</u> 15: 1713-1718
	C94	Zhou <i>et al.</i> (1998) "Determination of the Replication Error Phenotype in Human Tumors Without the Requirement for Matching Normal DNA by Analysis of Mononucleotide Repeat Microsatellites" <u>Genes, Chromosomes &amp; Cancer</u> 21: 101-107

479JAC2457/2.1022421-1

<b>EXAMINER</b>	<b>DATE CONSIDERED</b>
-----------------	------------------------